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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,262	08/27/2003	Yerramilli V.S.N. Murthy	61635-5016	6595

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,262	MURTHY ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 44-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 44-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 and 44-70 are pending in this application.

Applicants' arguments filed July 23, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al. U.S. Patent No. 5,719,197.

Kanios et al. teach compositions comprising a solvent and an active agent and a carrier. The solvents include fatty acids such as linoleic acid (column 4, lines 9-12) (identified as a water immiscible solvent in, for example, claim 11), fluoxetine (column 19, line 4) and 2-Hexyl Decanoic acid (column 30, line 24) (identified as a lipophilic counterion in, for example, claim 8). It does not recite these agents specifically as a "lipophilic counter ion" and "water immiscible solvent", however, "products of identical chemical composition (i.e. linoleic acid as a water immiscible solvent and decanoic acid as a lipophilic counterion) can not have mutually exclusive properties." A chemical

composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. their activity as a lipophilic counterion and a water immiscible solvent) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) Therefore it would have been obvious to employ fluoxetine, decanoic acid and linoleic acid in a composition motivated by the teaching of Kanios et al. who teach, *inter alia*, the same composition.

Claims 2-14, 45-54 and 56-57 are rejected as being indefinite to the extent that they read on the rejected base claims.

Claims 1, 44, 45-48, 50, 51, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shojaei et al. U.S. Patent No. 7,011,846 B2.

Shojaei et al. teach a composition for oral administration comprising an active compound such as fluoxetine (column 5, line 53) and the lipophilic counter ion, decanoic acid (see tables 1-3) and water immiscible solvent (see table 1, castor oil). Shojaei et al. differs in that it does not specifically identify the components and "lipophilic counter ions" and "water immiscible solvents". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It

would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as fluoxetine with a water immiscible solvent such as castor oil and a lipophilic counter ion such as decanoic acid motivated by the teaching of Shojaei et al. that the composition is successful in increasing the physical stability of the hydrophobic active agents (see abstract)

Claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. U.S. Patent No. 6,174,540 B1.

Williams et al. teach an injectable formulation comprising *inter alia* an active agent, such as antibiotics that are insoluble in water (oil soluble) and a water immiscible solvent, hydrogenated castor oil, and capric acid (a.k.a. decanoic acid) (see abstract). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It further differs in that it does not specifically teach the active agents in claims 4, 47 and 60, but it is noted that the long acting injectable agents of the patent are intended to solublize and release slowly an insoluble drug by solubilizing the agent in a

water immiscible solvent (castor oil) and a lipophilic counterion (capric acid, a.k.a. decanoic acid) as in the instant claims. It would have been made obvious to one of ordinary skill in art at the time it was made to combine a water insoluble active agent such as the recited antimicrobials (see column 1, lines 50-60) with a water immiscible solvent such as hydrogenated castor oil and a lipophilic counter ion such as capric acid (decanoic acid) motivated by the teaching of Williams et al. that the composition is a successful carrier for injectable agents that result in a long acting injection (see abstract).

Claims 1-8, 11, 12, 14, 44-51, 54, 55, 57-64, 67, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent No. 6,309,663 B1.

Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound

over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as gentamycin and fluoxetine (see column 30, lines 3 and 36) with a water immiscible solvent such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). motivated by the teaching of Patel et al. that the composition is a successful carrier for oral and injectable agents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 44-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65-138 of

copending Application No. 11/088922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 65 requires an active agent, a lipophilic counter ion and a pharmaceutically acceptable solvent, however, the claims contain the same elements as recited in the instant claims, e.g., active agents such as tilmicosin, lipophilic counter ions such as decanoic acid and solvents such as linoleic acid. The instant claims require elements such as e.g. active agents such as tilmicosin, a lipophilic counter ion such as decanoic acid and a water immiscible solvent such as linoleic acid (note linoleic acid is listed in the instant claims as a lipophilic counter ion and as a water immiscible solvent). None of the instant claims recites that specific combination, but instant claims 1-14 and 44-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical composition, the properties applicant discloses and/or claims (i.e. water immiscible solvent and lipophilic

counterion) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant asserts that Kanios does not disclose each and every feature of the invention recited in claim 1. In response to applicant's argument that the composition of Kanios is not disclosed for oral or injectable administration, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude the excipients recited in Kanios.

Applicant states that the phrase "to form a composition for oral administration or administration by injection excludes the Kanios reference because of excipients that are "sticky". In response, oral administration of an agent does not limit the formulation to those ingredients that are ingested. Oral administration would include administration of agents that are applied to the buccal cavity, and as such would require bioadhesives to adhere to the mucosal surface of the buccal cavity, such as bioadhesives and clay.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant asserts that Kanios recites a "laundry list", however the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude agents recited in Kanios. Further, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). Shojaei teaches fluoxetine as a compound that is hydrophobic and teaches that by combining with a water immiscible solvent such as castor oil and a lipophilic counter ion such as decanoic acid, the composition is successful in increasing the physical stability of the hydrophobic active agent (see abstract).

Applicant asserts that Shojaei does not disclose each and every feature of the invention or provide a reasonable expectation of success. In response, the features

that applicant claims are present in the prior art pharmaceutical compositions in the same amounts for the same purpose (topical use).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is not clear to the Examiner what picking and choosing is needed in order to determine what medicaments are specifically described in Shojaei to determine which agents are hydrophobic. All that is needed to implement the disclosure of Shojaei is to combine any hydrophobic agent recited (the patent is drawn to formulation of hydrophobic pharmaceutically active agents in a solubilizing composition) with the water immiscible solvents recited along with a decanoic acid. There does not appear to be any difficulty in arriving at the decision of which agent to choose.

Regarding Williams et al., applicant asserts that the capric acid disclosed is a capric acid triglyceride, which are esters of caprylic acid and capric acid, not capable of forming a salt with a pharmacologically active compound. However, there is nothing in the claim that limits the lipophilic counterion to form a salt with the pharmacologically

active compound. The claim recites a composition comprising a salt of the pharmacologically active compound with a lipophilic counterion and a water immiscible solvent. The lipophilic counterion can be an ionized form of a C_{10}-C_{22} saturated or unsaturated fatty acid. The caprylic acid of Williams et al. meets the claim limitations.

In response to applicant's argument that Patel et al. fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., forming a salt between a pharmacologically active compound and a lipophilic counterion) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant again states that the surfactants are part of a "laundry list" of active compounds. In response, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Exparte A,* 17. USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. *The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught.* The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. 102(a), in that publication.'). Id. at 1718. See also *In re Simvaramakrishnan,* 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)." In the instant case,

the species is hydrophilic agents in which simple dissolution is not sufficient to provide efficient bioabsorption of the therapeutic agent (see column 1, lines 13-31). Further, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bod*e 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is not clear to the Examiner what picking and choosing is needed in order to determine what medicaments are specifically described in Patel et al. to determine which agents are included as part of the invention. All that is needed to implement the disclosure of Patel et al. is to combine any of the agents recited (the patent is drawn to formulation of selected hydrophilic agents that have poor bioabsorption) with the water immiscible solvents recited along with a decanoic acid. There does not appear to be any difficulty in arriving at the decision of which agent to choose.

Regarding the non-statutory obviousness-type double patenting rejection over claims 65-138 of co-pending 11/088,922, applicant has requested that the rejection be held in abeyance until all rejections of the claims over prior art have been addressed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Wagoe
Patent Examiner
Art Unit 1614

November 8, 2007

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER